

GNT

**National List Petition Submission
For Edible Fruit and Vegetable Juice Color**

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USDA NATIONAL
ORGANIC PROGRAM
2006 JUN 23 A 10:00

EXBERRY® Fruit and Vegetable Juice color

June 20, 2006



GNT USA, Inc.
660 White Plains Road
Tarrytown, NY 10591

June 20, 2006

Arthur Neal
USDA/AMS/TM/NOP
Room 4008-So.
Ag Stop 0268
1400 Independence Avenue SW
Washington, DC 20250

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USDA NATIONAL
ORGANIC PROGRAM
2006 JUN 23 A 10:01

Subject: National List Petition Submission for Edible Fruit and Vegetable Juice Color.

Dear Mr. Neal:

GNT USA Inc. is petitioning edible fruit and vegetable juice colors for inclusion on the National List under Section 205.606:

Agricultural (nonorganic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)".

Fruit and vegetable juice colors are classified by the F.D.A as "exempt from certification" under 21CFR73.250, fruit juice color and 21CFR73.260, vegetable juice color.

The proposed criteria for this category are as follow:

- The colors have to be manufactured from fruits and vegetables
- The process has to be exclusively physical without any synthetic aid or adjuvant.
- The production methods have to be certified organic under the USDA-NOP standards.

Attached, please find the completed forms as well as the Material Safety Data Sheet, the Statement on Residue and the Organic Production Methods Certificate for EXBERRY® fruit and vegetable juice colors.

If further information is required, please contact our main office in Tarrytown, New York at 914.524.0600.

Sincerely,


Amelie Hayte

EXBERRY® - Fruit and Vegetable Juice for Color
produced and distributed by GNT Group
classified under 21CFR73.250 & 21CFR73.260

ITEM A

The substance is being petitioned for inclusion on the National List under Section 205.606:

Agricultural (nonorganic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)."

ITEM B

1. EXBERRY® fruit and/or vegetable juices for color

2. Manufactured by:

GNT Nederland B.V.
Industrieweg 26
5731 HR Mierlo
The Netherlands
+31-492-663952

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3. Intended and current use of the substance:

Food ingredient having coloring properties

4. The substance is being used as a food ingredient having coloring properties in diverse foods and beverages. The substance is added during the processing of the food product to impart color throughout the shelf life of the product.

EXBERRY® - Fruit and Vegetable Juice for Color
produced and distributed by GNT Group
classified under 21CFR73.250 & 21CFR73.260

5. The sources of the food ingredients are edible fruits and vegetables, which include but are not limited to:

Aronia	Black currant	Grape	Strawberry	Purple potato
Beet	Carrot	Pumpkin	Elderberry	Blueberry
Spinach	Hibiscus	Cherry	Red cabbage	Tomato

The production process is on an entirely physical basis such as crushing, pressing, filtering and concentration by vacuum evaporation. Water, invert sugar and citric acid may be added during the manufacturing process.

6. Reviews by State, private certification programs or organizations:

GNT Nederland B.V., the production site of GNT Group, is under review and/or certification of the following organizations

- Dutch Food and Consumer Product Safety Authority (Voedsel en Waren Autoriteit - VWA)
- DNV Nederland - certification body for ISO 9001:2000, Dutch HACCP and GMP
- Skal Certification Organic Production - organic production and certification in the Netherlands are based on the EU-regulation (EEC) nr. 2092/91
- Skal Control Union World Group - organic production and certification in the Netherlands according to USDA Organic and NOP

7. FDA registration number: 18189116412

8. The Chemical Abstract Service (CAS) is not applicable.

The substance falls under the F.D.A regulation for "colors exempt from certification" 21CFR73.250, fruit juice color and 21CFR73.260, vegetable juice color. The label of the product that contains the petitioned substance is "fruit and vegetable juice for color".

EXBERRY® - Fruit and Vegetable Juice for Color
produced and distributed by GNT Group
classified under 21CFR73.250 & 21CFR73.260

9. N/A. The substance is intended for food application. It is 100% natural and is not formulated or processed with any synthetic aid or adjuvant

10. See enclosed Material Safety Data Sheet (MSDS)

11. The substance is made from fruits and vegetables, which have a well-known history of consumption and which are Generally Recognized As Safe (GRAS).

12. Justification Statement

The use of EXBERRY® fruit and vegetable juice color is currently necessary in organic products, as no organic alternative is available yet. The addition of color during the processing of organic products is essential in order to enhance the color that could be lost during the processing or throughout the shelf life of the product.

All other colors that are from non-synthetic sources are processed or formulated with the aid of synthetic substances. To avoid any synthetic ingredients in organic food, only EXBERRY® fruit and vegetable juice colors can be used to impart color and answer consumers' demand. The substance petitioned herein is 100% natural and processed by physical means, without any synthetic aid or adjuvant. The production methods are certified organic under the U.S.D.A-N.O.P standards.

Currently, only non-organic EXBERRY® fruit and vegetable juice colors are available, as there are not enough organic farmers or organic fields to produce the raw materials in the quantity requested by the food industry. To produce the necessary amount of organic fruits and vegetables, farmers and fields have to be converted to the organic methods. The surface necessary for the production of organic fruits and vegetables would have to double, due to yield decrease as well as other unknown factors. Internal research of the GNT Group has estimated that ten years would be necessary to convert twenty percent of the EXBERRY® color production to organic.

13. Confidentiality

The process flow diagram (page 15) is to be considered as Confidential Business Information (CBI) on the basis of "Trade secret" for the production process.

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance: Fruit and vegetable juice color

Question	Yes	No	N/A ¹	Documentation (TAP, petition, regulatory agency, other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		✓		The substance is not synthetic. It is derived from fruits and vegetables only, processed by physical means like crushing, pressing, filtering and concentration by vacuum evaporation (See attached process flow chart). During the processing, no chemical solvents are used. The production is GMP certified and organic wastes are used for animal feed according to specific EC legislation related to the animal feed sector.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518m.3]		✓		All raw materials and processing adjuvant are derived from all-natural sources. The production methods are certified organic under the USDA-NOP standards. (See attached certificate)
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		✓		The substance is manufactured from natural sources only and is therefore not harmful to the environment.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			✓	The substance contains only the natural constituents of the processed fruit and vegetables. Citric acid and invert sugar may be used for standardization purposes and these ingredients are recognized as GRAS.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		✓		There is no indication for detrimental chemical interaction of fruit and vegetable extracts with other materials.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			✓	This substance is intended for food application
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			✓	This substance is intended for food application
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		✓		The substance is from natural sources only (fruits, vegetables, citric acid, invert sugar, water). Citric acid and invert sugar may be used for standardization purposes and these ingredients are recognized as GRAS.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		✓		This substance is intended for food application. In case of accident-caused release the products are completely biodegradable.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		✓		The substance is actually beneficial for human health. It is fruit and vegetable based and rich in antioxidants like e.g. anthocyanins, carotenoids and other phytochemicals.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		✓		The substance is manufactured from natural sources that have been consumed for years on a daily basis. Furthermore, the raw materials are known to have beneficial effects on human health.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		✓		Currently, there is no GRAS exemption for color additives. For the F.D.A., all colors are considered artificial and are categorized under "certified" or "exempt from certification".
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		✓		See attached statement on residues

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production?
Substance: Fruit and vegetable juice color

Question	Yes	No	N/A ¹	Documentation (TAP, petition, regulatory agency, other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]		✓		The substance is formulated from natural sources only and is processed only with water and physical processing. The production methods are certified organic under the USDA-NOP standards.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		✓		The process is not intended to chemically change the substance. The fruits and vegetables are concentrated with the help of water and physical processing. Therefore, the properties of the substance are similar to the properties of the fruits and vegetables.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		✓		The substance itself does not occur naturally, but it only contains natural constituents of the processed fruit and vegetables.
4. Is there a natural source of the substance? [§205.600 b.1]			✓	The substance is 100% natural. It is not formulated or processed with any synthetic aid or adjuvant
5. Is there an organic substitute? [§205.600 b.1]		✓		The amount of raw materials that is processed for fruit and vegetable juice color is not commercially available as organic. A period of 10 years has been estimated as a minimum to be able to produce organically the amount of raw materials necessary.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			✓	The substance is 100% natural. It is not formulated or processed with any synthetic aid or adjuvant.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			✓	The substance is 100% natural. It is not formulated or processed with any synthetic aid or adjuvant.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	✓			The substance is 100% natural but cannot be produced organically yet, as the raw materials are not commercially available as organic. Only The production methods are certified organic under the USDA-NOP standards. (see attached certificate)
9. Is there any alternative substances? [§6518 m.6]		✓		All other colors "exempt from certification" are non-organic and are processed or formulated with the aid of synthetic substances. To avoid any synthetic ingredients in organic food, only organic, or as an interim solution non-organic, fruit and vegetable juice colors can be used to impact color and partly nutritive values to consumers' food.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		✓		The substance is needed, as no organic color is available yet. Only time is necessary to have enough farmers and lands to produce fruit and vegetable organically in the quantity requested by the food industry and the consumers.

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices?

Substance: Fruit and vegetable juice color

Question	Yes	No	N/A	Documentation (TAP, petition, regulatory agency, other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	✓			The substance is currently used in organic products. E.g. organic yogurt, ice cream, juices, dried fruits, etc.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			✓	The substance is from natural sources only and does not contain any synthetic ingredients or processing aid like solvents or emulsifiers. The production methods are certified organic under the USDA-NOP standards.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	✓			Since the substance is derived only from natural sources it is compatible with sustainable agriculture and production.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	✓			The substance does contain almost all natural and valuable constituents of the processed fruits and vegetables.
5. Is the primary use as a preservative? [§205.600 b.4]		✓		This is not a preservative
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			✓	This substance is not formulated or processed with any synthetic aid or adjuvant. This is a food having coloring properties.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		✓		
a. copper and sulfur compounds;		✓		
b. toxins derived from bacteria;		✓		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		✓		
d. livestock parasiticides and medicines?		✓		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		✓		

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB RECOMMENDED DECISION

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: _____	Substance: _____																								
<p>A. Evaluation Criteria (Documentation attached; committee recommendation attached)</p> <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <p>1. Impact on humans and environment</p> <p>2. Availability criteria</p> <p>3. Compatibility & consistency</p> </td> <td style="width: 50%; vertical-align: top;"> <p>Criteria Satisfied?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</p> </td> </tr> </table>		<p>1. Impact on humans and environment</p> <p>2. Availability criteria</p> <p>3. Compatibility & consistency</p>	<p>Criteria Satisfied?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/> (see B below)</p>																						
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NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: _____	Substance: _____																								
Committee: Crops <input type="checkbox"/> Livestock <input type="checkbox"/> Handling <input type="checkbox"/>																									
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MATERIAL SAFETY DATA SHEET

EXBERRY®

Generic MSDS for EXBERRY® Products

Product No. : not applicable

May be used to comply with OSHA's Hazard Communication Standard. 29 CFR 1910.1200 Standard must be consulted for specific requirements. If any item is not applicable, or no information is available, the space must be marked to indicate that.

SECTION I. Product Identification

Manufacturer's name: **GNT International B.V.**

Telephone number: +31 - (0)492 668141

Address: P.O. Box 94, 5731 AB Mierlo, The Netherlands

Product name: **EXBERRY® Generic MSDS for EXBERRY®**
Product No. : not applicable

Botanical family: not applicable

Formula: Preparation manufactured from:
fruits invert sugar
vegetables citric acid

SECTION II. Hazardous ingredients/Identity Information

Specific chemical identity; CAS #; ACGIH TLV (Units); OSHA PEL (Units); STEL (Units)

Not applicable. Foodstuff.

SECTION III. Physical/Chemical Characteristics

Boiling point: 215-230 °F

Vapor pressure: < 50 mbar (70 °F)

Vapor density (AIR=1): not available

Solubility in water: soluble

Material Safety Data Sheet No.: USA-not applicable 13/6/06

page 10 of 15

EXBERRY® is a registered Trade Mark of GNT mbH, Germany
EXBERRY® Natural Colors are produced by GNT Nederland B.V., Netherlands

The information contained herein or any other information given by us is, to the best of our knowledge and belief, accurate. However, since the conditions of handling and use are beyond our control, we do not guarantee any results, and we are not liable for any damage incurred by following these suggestions. Nothing contained herein is to be construed as a recommendation for use in violation of any patents or of applicable laws or regulations.

GNT USA, Inc. • 660 White Plains Road • Tarrytown, New York 10591
Telephone 914.524.0600 • Telefax 914.524.0681 • www.gntusa.com

GNT

Appearance and odor:	viscous and aromatic
Specific gravity (H ₂ O=1):	1,28 - 1,38
Percent volatile, by volume (%):	not available
Evaporation rate (butyl acetate=1):	not available (very small)
Freezing point:	less than 0 °F

SECTION IV. Fire and Explosion Hazard Data

Flash point (method used):	not available
Flammable limits:	not available
LEL:	not available
UEL:	not available
Extinguishing media:	water etc.
Special fire fighting procedures:	not necessary
Unusual fire and explosion hazards:	none known

SECTION V. Reactivity Data

Stability	
Unstable:	no
Stable:	yes
Conditions to avoid:	not applicable
Incompatibility (materials to avoid):	strong acids and bases, sulfides and sulfites
Hazardous polymerization	
May occur:	no
Will not occur	certain
Conditions to avoid:	not applicable

SECTION VI. Health Hazard Data

Route(s) of entry	
Inhalation:	no
Skin:	no
Ingestion:	yes
Health hazards (acute and chronic)	
Carcinogenicity:	no
NTP:	no
LARC monographs:	no
OSHA regulated:	no
Signs and symptoms of exposure:	foodstuff, no health hazards

Material Safety Data Sheet No.: USA-not applicable 13/6/06

page 11 of 15

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The information contained herein or any other information given by us, to the best of our knowledge and belief, accurate. However, since the conditions of handling and use are beyond our control, we do not guarantee any results, and we are not liable for any damage incurred by following these suggestions. Nothing contained herein is to be construed as a recommendation for use in violation of any patents or of applicable laws or regulations.

GNT USA, Inc. • 660 White Plains Road • Tarrytown, New York 10591
Telephone 914.524.0600 • Telefax 914.524.0681 • www.gntusa.com

GNT

Medical conditions generally aggravated by exposure:

In case of contact with eyes, remove contact lenses and rinse immediately with plenty of water. Contact physician if irritation persists.

Emergency and first aid procedures:

not necessary

SECTION VII. Precautions for Safe Handling and Use

Steps to be taken in case material is released or spilled: clean with water

Waste disposal method: same as foodstuffs. Observe local, State and Federal Regulations. Do not incinerate sealed containers.

Precautions to be taken in handling and storing: special precautions are not necessary.

Other precautions: not necessary

SECTION VIII. Control Measures

Respiratory protection (specify type)

Ventilation

Local exhaust:	not necessary
Special:	not necessary
Mechanical:	not necessary
Other:	not necessary

Protection gloves: not necessary (strong coloring foodstuff)

Eye protection: not necessary

Other protective clothing or equipment: not necessary

Work/hygienic practices: same as foodstuffs



STATEMENT ON RESIDUES

GNT USA Inc. hereby confirms that:

The raw materials used for EXBERRY® products originate from direct cultivation and suppliers are obliged to comply with the legal European requirements governing the cultivation of fruits and vegetables. Other raw materials of supplying companies have to comply to the current European legislations for the specific material before it is purchased.

Pesticides:

Any pesticide residues left on or in the raw materials designed for the manufacture of EXBERRY® products do not exceed the maximum residue limit specified in the *Council Directive 90/642/EEC of November 27, 1990* on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables and its amendments.

Any pesticide residues in our EXBERRY® products do not exceed the maximum residue limits specified in the *Directive 90/642/EEC* (and amendments).

So far, neither organochlorine pesticides nor organophosphorus pesticides have been traced in our products. The same applies to other pesticide residues, with the current limits of determination being as follows:

- ... organochlorine pesticides: 0.001 - 0.005 mg/kg
- ... organophosphorus pesticides: 0.005 - 0.010 mg/kg
- ... other pesticide residues: 0.005 - 0.010 mg/kg

Heavy metals:

Regarding the maximum levels for heavy metals there are no defined maximum levels for our EXBERRY® products (fruit and vegetables concentrates) within the European legislation.

However, our EXBERRY® products do not exceed the following max levels:

Arsenic	< 3 mg/kg
Cadmium	< 1 mg/kg
Mercury	< 1 mg/kg
Lead	< 10 mg/kg
Heavy metals (as lead)	< 40 mg/kg

Mycotoxins:

Our EXBERRY® products are in compliance with the current European food legislation (*Directive 1525/97/EC, 194/97/EC, etc.*).

To ensure compliance with the above mentioned regulations, all raw materials and semi-finished products designed for the production of EXBERRY® products are regularly screened for pesticide residues, heavy metals and other contaminants.

The frequency of the analyses depends on the processing of the raw materials. The raw materials for EXBERRY® products are normally processed per campaign or season, depending on the amount of processed raw material an appropriate number of samples are taken and analysed.

CERTIFICATE

CERTIFICATE N°: C803789NOP-01.2005
REGISTRATION N°: SKAL-INT 803789

Field of attention:

**Organic production methods
USDA-NOP**

Issued to:

**GNT Nederland BV
Mierlo, NETHERLANDS
Project in: NETHERLANDS**

Standard:

**The National Organic Programme of the United States Department of Agriculture and Skal
International Standards**

Date of certification: 9 November 2005

Skal International declares to have inspected the unit(s), and/or product(s) of the above mentioned client, and have found them in accordance with the standards mentioned above. This certificate covers the unit(s), and/or product(s) as mentioned in the authenticated annex of this certificate.

This certificate is in force until further notice, provided that the above-mentioned client continues meeting the conditions as laid down in the client contract with Skal International. Based on the annual inspections that Skal International performs, this certificate is updated and kept into force.

Date of certification:
9 November 2005

Place and date of issue:
Zwolle, 9 November 2005



Skal International is officially
accredited by the United States
Department of Agriculture

Delegated by:

On behalf of the Managing
Director

Mr. J. Huisman
Certifier

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Full Page

PROCESS FLOW DIAGRAM

EXBERRY® Fruit and Vegetable Juice Color

Confidential

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EXBERRY® is a registered Trade Mark of GNT International B.V., Netherlands

EXBERRY® is produced by GNT Nederland B.V., Netherlands

The information contained herein or any other information given by us is, to the best of our knowledge and belief, accurate. However, since the conditions of handling and use are beyond our control, we do not guarantee any results, and we are not liable for any damage incurred by following these suggestions. Nothing contained herein is to be construed as a recommendation for use in violation of any patents or of applicable laws or regulations.